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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,117	MULLALLY, JOHN P.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *10-13 and 15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☒ Claim(s) *5-7 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on October 29, 2007 is acknowledged. The traversal is on the ground(s) that both the group I and II inventions are classified in the same class and subclass. Applicant asserts that it would not be an additional burden on the Examiner to search both groups at the same time. This is not found persuasive because these inventions are distinct/unrelated for the reasons in the restriction requirement dated September 25, 2007 and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Moreover, because a search of each distinct/unrelated invention would not be coextensive with the other(s), and because each invention will require its own separate patentability analysis, an examination and search of multiple inventions in a single application would constitute a serious undue burden on the examiner.

It should be remembered that the purpose of an election of species requirement is to simplify the search and issues considered during prosecution, and that because this is so the ultimate allowance of a generic claim will encompass all additional species within the scope of the allowed genus. Stated alternatively, the purpose of an election of species requirement, as opposed to a restriction between claim groups, is to reduce the burden on the examiner during prosecution only; a full search is merely postponed until allowance of the generic claim.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-13 and 15-20 are **withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 29, 2007.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-9 and 14 are presented for examination.

Claim Objections

Claim 5 is objected to because of the following informalities: the word loratadine is misspelled. Appropriate correction is required.

Claim 6 is objected to because of the following informalities: the word acetonide is misspelled. Further, there is a misplaced comma. It appears that acetoniode (sic) is a separate agent, however, the specification, on page 5, paragraph 19 states that the agent is triamcinolone acetonide, not triamcinalone, acetoniode (sic). Appropriate correction is required.

Claim 7 is objected to because of the following informalities: the word fluticasone is misspelled. Appropriate correction is required.

Applicant is advised that should claim 5 be found allowable, claim 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "leukotriene inhibitor" in claim 4 is used by the claim to mean a plethora of antibiotics, steroids, theophylline, vaccine and other miscellaneous drug categories, while the accepted meaning is "montelukast and zafirlukast." The term is indefinite because the specification does not clearly redefine the term.

The term "antihistamine" in claim 6 is used by the claim to mean "mometasone furoate monohydrate, triamcinalone, acetoniode, budesonide and azelastine", while the accepted meaning is "azelastine." The term is indefinite because the specification does not clearly redefine the term. Azelastine is the only agent is this Markush group that is actually an antihistamine.

Claim 7 is rejected because the examples set forth in the specification are insufficient to justify the scope of the claim. The instant specification, at page 5, paragraph 21 gives support for each of the antihistamines to be administered in the alternative. The claim is drafted so that it appears that all of the antihistamines are administered together. Correction is required.

Claim 8 is rejected because it is a dependent claim that fails to disclose which claim it depends from rendering the scope of the claim indeterminate.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipworth et al. (U).

Lipworth et al. teach that there is an association between allergic inflammation in the upper airway and the lower airway and up to 40% of patients with asthma have allergic rhinitis and vise versa and since one will affect the other, neither condition should be treated in isolation (page 878, column 1, 1st paragraph).

Further, Lipworth et al. teach administration of leukotriene inhibitors such as montelukast and zafirlukast along with loratadine (page 878, column 2) and propose treatment options to include the use of the combined mediator blockade (antihistamine and leukotriene inhibitor) to facilitate the use of lower maintenance doses of topical corticosteroid. Recited corticosteroids include budesonide and mometasone (page 879, column 1).

Regarding the reduction of C-reactive protein, the recitation of the treatment of individuals "in need" of the treatment of a certain condition is missing. A physician will typically examine many patients with various pathologies, and only some will have a particular disease requiring a particular treatment. It has been traditional in United States practice to recite the treatment of individuals "in need" of the treatment of a certain condition so as to indicate that particular subset of patients actually in need of intervention; an alternative is to recite the treatment of an individual "suffering from" a given disease. Accordingly, the following format is preferred for claiming methods of treating: "A method for treating disease X comprising administering to an individual suffering from/in need of such treatment an effective amount of agent Y". Claims not specifying the subset of patients to be treated in this manner are generally viewed as being anticipated by any prior art method using a given agent since they read on administration to the general population and not a specified subset requiring treatment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipworth et al. (U), Ridker et al. U.S. Patent No. 6,040,147 A and Faham et al. U.S. Patent No. 6,723,348 B2.

Lipworth et al. teach that there is an association between allergic inflammation in the upper airway and the lower airway and up to 40% of patients with asthma have allergic rhinitis and vise versa and since one will affect the other, neither condition should be treated in isolation (page 878, column 1, 1st paragraph).

Further, Lipworth et al. teach administration of leukotriene inhibitors such as montelukast and zafirlukast along with loratadine (page 878, column 2) and propose treatment options to include the use of the combined mediator blockade (antihistamine and leukotriene inhibitor) to facilitate the use of lower maintenance doses of topical

corticosteroid. Recited corticosteroids include budesonide and mometasone (page 879, column 1). Lipworth teach effective doses of leukotriene inhibitor (montelukast 10 mg/day) and cetirizine (10 mg/day) as well as budesonide and mometasone 400µg daily and 200 µg daily (page 879, column 1).

It differs in that Lipworth et al. does not teach the reduction of C-reactive protein. Ridker et al. teach that C-reactive protein is a marker for underlying systemic inflammation (column 1, lines 60-61). It would have been obvious to employ the leukotriene inhibitors, antihistamines and corticosteroids of Lipworth et al. to reduce C-reactive protein in the body of the user motivated by the teaching of Lipworth that there is an association between allergic inflammation in the upper and lower airway and the teaching of Ridker et al. that C-reactive protein is a marker for underlying systemic inflammation. As such, as the inflammation is reduced, the C-reactive protein level would be reduced.

Regarding the fexofenadine of instant claim 7 and antihistamine dosages recited in claims 2 and 3, Faham et al. teach fexofenadine is an antihistamine (column 1, lines 28-30) and is administered in doses of from about 10 mg to about 500 mg/day (column 8, lines 36-47). This amount overlaps and encompasses the claimed amount of about 150 to about 250 mg. A *prima facie* case of obviousness exists where the claimed ranges are close enough that one skilled in the art would have expected them to have the same properties.

Regarding the combination of antihistamines in instant claim 7, as stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

Regarding the amount of corticosteroid in instant claims 2 and 3, Lipworth disclose 200 and 400 µg/day. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment , the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. As such, it would have been made obvious to one of ordinary skill in art at the time it was made to employ the recited amounts of corticosteroid motivated by the teaching of Lipworth et al. that dosages of corticosteroids can be lower when combined with a leukotriene inhibitor and an antihistamine for allergic inflammation.

Regarding claim 6, the nasal antihistamine, azelastine is disclosed in Lipworth et al. for the treatment of rhinitis.

Regarding claim 7, Ridker et al. teach fluticasone as an anti-inflammatory agent useful for reducing C-reactive protein (column 7, line 30).

Regarding the administration of the leukotriene and antihistamine orally and the steroid nasally infused, Lipworth et al. teach that treatment of allergic airway inflammation in the nose with topical corticosteroids may be associated with a commensurate improvement in bronchial hyper responsiveness and asthma control

(page 878, column 1). Oral leukotriene inhibitors and loratadine are also disclosed (page 878, column 2).

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

March 3, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614